

CAREALL DIPHENHYDRAMINE- diphenhydramine hydrochloride tablet, coated
New World Imports, Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredient

Diphenhydramine HCl 25mg

Purpose

Antihistamine

Keep out of reach of children

In case of accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) immediately.

Uses

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

Sneezing, runny nose, itchy / watery eyes, and itching of the nose or throat

Temporarily relieves these symptoms associated with the common cold:

Sneezing, runny nose

Warnings

Do not use with any other products containing diphenhydramine, including ones used on skin

Ask a doctor before use if you have:

A breathing problem such as emphysema or chronic bronchitis

Glaucoma

Trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product:

Marked drowsiness may occur

Avoid alcoholic beverages

Alcohol, sedatives, and tranquilizers may increase drowsiness

Be careful when driving a motor vehicle or operating machinery

Excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use

Directions

Take every 4 to 6 hours, or as directed by a doctor. Do not take more than 6 times in 24 hours

Adults and children 12 years of age and older: 1 to 2 caplets

Children 6 to 12 years: 1 caplet

Children under 6: do not use

Inactive Ingredients

croscarmellose sodium, D C Red 27 aluminum lake, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, titanium dioxide

NDC 51824-056 -01

CAREALL

Complete Allergy Relief

Antihistamine

RELIEVES

Sneezing

Itchy/watery eyes

Runny nose or itchy throat due to allergy & colds

100

Diphenhydramine HCl Caplets

25mg each

Compares to the active ingredient in BENADRYL®

Your Source For High Quality

Drug Facts

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg, Antihistamine

Purpose

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

sneezing

runny nose

itchy, watery eyes

itching of the nose or throat

these symptoms associated with the common cold:

sneezing

runny nose

Warnings

Do not use with any other product containing diphenhydramine, including ones used on skin

Ask a doctor before use if you have

a breathing problem such as emphysema or chronic bronchitis

glaucoma

trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

Continued Under Label

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Benadryl®.

Distributed By: MWI, Inc., 160 Athens Way, Nashville, TN 37228

085317004767

Lot: R0416

Exp: 7

PEEL HERE

Drug Facts (Continued)

When using this product

marked drowsiness may occur

avoid alcoholic beverages

alcohol, sedatives, and tranquilizers may increase drowsiness

be careful when driving a motor vehicle or operating machinery

excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.

In case of accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) immediately.

Directions

take every 4 to 6 hours, or as directed by a doctor

do not take more than 6 times in 24 hours

adults and children 12 years and over: 1 to 2 caplets

children 6 to under 12 years: 1 caplet

children under 6 years of age: do not use

Other information

each caplet contains: 20mg calcium

store at room temperature 20° – 25°C (68° – 77°F)

do not use if safety seal under cap is broken or missing

Inactive ingredients

croscarmellose sodium, D&C red #27 aluminum lake, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, titanium dioxide

CAREALL DIPHENHYDRAMINE			
diphenhydramine hydrochloride tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51824-056
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	Diphenhydramine Hydrochloride	25 mg

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
Magnesium Stearate (UNII: 70097M6I30)	
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	pink (Bright Pink)	Score	no score
Shape	OVAL (Oval in Shape, sides straight, top and bottom rounded)	Size	11mm
Flavor		Imprint Code	048;D
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-056-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/28/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/28/2016	

Labeler - New World Imports, Inc (075372276)